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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/614,722	07/07/2003	Edgardo Costa Maianti	DID1044US	7562

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EXAMINER

CRAIG, PAULA L

ART UNIT	PAPER NUMBER
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3761

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/614,722

Applicant(s)

MAIANTI ET AL.

Examiner

Paula L. Craig

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 November 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) 6-8 and 10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/21/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. The objection to the specification and the drawings is withdrawn. The rejections of Claims 1-5 on the ground of provisional double patenting are withdrawn in light of the terminal disclaimer filed over copending Application No. 10/805,165. Applicant's arguments with respect to the remaining rejections of Claims 1-5 and 9 have been considered but are moot in view of the new grounds of rejection.

Election/Restrictions

2. As indicated in the prior Office Action mailed June 7, 2006, Claims 6-8 and 10 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 1-5 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Raible (U.S. 5,770,149) in view of U.S. Patent Application Publication No. 2002/0057990 to Ghelli et al.

6. For Claim 1, Raible '149 teaches a device for treating blood in an extracorporeal circuit including a venous blood reservoir having an inlet and an outlet (extracorporeal blood oxygenation system 10 and reservoir 111, Figs. 3 and 8-9a, col. 1, lines 7-13, col. 3, lines 55-62, col. 5, lines 18-38, col. 12, lines 8-52, col. 13, line 60 to col. 14, line 5). Raible teaches a heat exchanger having an inlet and an outlet (heat exchanger portion, including heat exchanger tubes 54 and heat exchanger cavity 50; Figs. 3, 7, and 8-9a, col. 6, lines 11-26, col. 7, line 1 to col. 9, line 7). Raible teaches a pump having an inlet and an outlet (pump includes pump impeller housing cavity 30 or 30a, pump impeller 40 or 40a, motor drive component 14, Figs. 3 and 8-9a, col. 5, line 18 to col. 6, line 37). Raible teaches an oxygenation apparatus having an inlet and an outlet (membrane oxygenator portion, including gas-exchange cavity 72 and gas exchange membranes 74; Figs. 3 and 8-9a, col. 3, lines 31-55, col. 8, line 1 to col. 9, line 17). The device has an arterial blood filter having an inlet and an outlet (arterial filter apparatus 128 and chamber 126, Figs. 9-9a, col. 3, line 63 to col. 4, line 4, col. 12, line 55 to col. 13, line 41, col. 15, lines 17-25). Raible teaches the venous blood reservoir, heat exchanger, pump, oxygenation apparatus, and arterial blood filter being integrated into a single

monolithic assembly (Figs. 3 and 8-9a, col. 1, line 16 to col. 2, line 10). Raible does not teach the pump having an inlet connected to receive blood from the outlet of the heat exchanger. However, it is well known in the art to vary the order in which the components of a device for extracorporeal blood treatment are connected; it is also well known in the art to include pumps at various points between the components of the system as needed to keep the blood flowing. Ghelli confirms this and teaches a device for treating blood in an extracorporeal circuit having a venous blood reservoir, a heat exchanger, a pump, an oxygenation apparatus, and an arterial blood filter (Fig. 7, paragraphs 1-3, 14, 24-27). Ghelli teaches the integration of these components into a single monolithic assembly to save space in the vicinity of the operating field (Fig. 7 and paragraphs 2-3, 24-27). The device of Ghelli has the pump inlet connected to receive blood from the outlet of the heat exchanger (Fig. 7, paragraph 24). Ghelli teaches that this arrangement allows the pump and heat exchanger to be positioned within and surrounded by the oxygenation apparatus, providing for maximum reduction of space occupation and compactness (paragraphs 24-26). Applicant's specification does not disclose that blood flow through the heat exchanger and then the pump, rather than the pump first and then the heat exchanger, serves any stated purpose or solves any particular problem. Applicant's specification includes an embodiment of the invention in which the pump is placed before the heat exchanger (specification, Fig. 5). See *In re Dailey and Eilers*, 149 USPQ 47 (CCPA 1966). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Raible '149 to have the pump inlet connected to receive blood from the outlet of the heat exchanger, as taught

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by Ghelli, to allow the pump and heat exchanger to be positioned within and surrounded by the oxygenation apparatus, providing for compactness to save space in the vicinity of the operating field, as taught by Ghelli.

7. For Claim 2, Raible '149 teaches a cardiotomy reservoir that is monolithically connected to the venous blood reservoir (reservoir 111 and defoamer/filter element 122 receives blood from either venous blood return inlet 120 or cardiotomy blood inlet 122, Figs. 8-8a, col. 12, lines 8-52).

8. For Claim 3, Raible '149 teaches the outlet of the venous reservoir being connected to the inlet of the heat exchanger, the outlet of the heat exchanger being connected to the inlet of the pump, the outlet of the pump being connected to the inlet of the oxygenation apparatus, and the outlet of the oxygenation apparatus being connected to the inlet of the arterial filter (Figs. 3 and 8-9a, col. 5, lines 18-43, and col. 12, lines 8-67; note the claim does not require direct connection, nor that blood flow directly from one component to another).

9. For Claim 4, Raible '149 teaches the device including a first hollow cylindrical structure for containing a blood oxygenation structure, wherein the first hollow cylindrical structure is suitable to accommodate the heat exchanger, and wherein the first hollow cylindrical structure supports the venous blood reservoir and the pump, respectively, at the upper end face and at the lower end face, and wherein the device includes a second hollow cylindrical structure monolithically connected to the first hollow cylindrical structure and being suitable to contain a filtration structure for filtering the arterial blood (first hollow cylindrical structure is housing 20; second hollow cylindrical structure is

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housing 18b, including the outer wall of arterial filter chamber 126; Figs. 3 and 7-9a, col. 3, line 55 to col. 4, line 4, col. 12, line 55 to col. 13, line 21, col. 15, lines 17-25).

10. For Claim 5, Raible '149 teaches the device including a first hollow cylindrical structure which accommodates the heat exchanger and supports the venous blood reservoir and the pump so as to arrange in a coaxial and directly facing configuration the outlet of the venous blood reservoir and the inlet of the heat exchanger, and the outlet of the heat exchanger with the inlet of the pump (Figs. 3 and 8-8a, col. 5, lines 18-28, col. 12, lines 8-52).

11. For Claim 9, Raible '149 teaches a pulsating pump (peristaltic pump, col. 9, lines 45-56). Raible '149 does not expressly teach the pulsating pump being the pump connected to receive blood from the outlet of the heat exchanger. Ghelli teaches a pulsating pump receiving blood from the outlet of the heat exchanger (pumping unit 1, Fig. 7, paragraphs 15 and 21-24). Ghelli teaches that the pulsating pump provides for compactness in the device (paragraph 26). It would have been obvious to one of ordinary skill in the art to modify Raible '149 to include a pulsating pump receiving blood from the outlet of the heat exchanger, as taught by Ghelli, to provide for compactness in the device, as taught by Ghelli.

Conclusion

12. Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paula L. Craig whose telephone number is (571) 272-5964. The examiner can normally be reached on 8:30AM-4:00PM M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Paula L Craig
Examiner
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PLC

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read 'Tatyana', is written over the printed name and title of the examiner.